### STATE OF NEW YORK

### **DIVISION OF TAX APPEALS**

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In the Matter of the Petition

of :

PHARMACIA & UPJOHN COMPANY : DETERMINATION DTA NO. 818583

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for Revision of a Determination or for Refund of Sales and Use Taxes Under Articles 28 and 29 of the Tax Law for the Period March 1, 1996 through February 28, 1999.

Petitioner, Pharmacia & Upjohn Company, Tax Unit 8330-088-112, 7000 Portage Road, Kalamazoo, Michigan 49001-0102, filed a petition for revision of a determination or for refund

of sales and use taxes under Articles 28 and 29 of the Tax Law for the period March 1, 1996

through February 28, 1999.

On February 19 and 25, 2002, respectively, petitioner by its representative, McDermott, Will & Emery (Arthur R. Rosen, Esq., of counsel), and the Division of Taxation by Barbara G. Billet, Esq. (James Della Porta, Esq., of counsel), waived a hearing and agreed to submit the matter for determination based on documents and briefs to be submitted by August 9, 2002, which date commenced the six-month period for the issuance of this determination. After review of the evidence and arguments presented, Thomas C. Sacca, Administrative Law Judge, renders the following determination.

# **ISSUE**

Whether Pharmacia & Upjohn Company is entitled to a refund of sales and use tax paid with respect to packaging materials and informational inserts used in the distribution of sample drugs and medicines to physicians and other health care providers during the period at issue.

### FINDINGS OF FACT

The parties executed a Stipulation of Facts in connection with this proceeding. These stipulated facts are set forth as Findings of Fact herein.

- 1. Petitioner was incorporated under the laws of the State of Delaware on September 5, 1958. Petitioner's Federal Employer Identification Number is 38-1123360C. During the audit period, petitioner was commercially domiciled in Kalamazoo, Michigan and was primarily engaged in the business of developing, manufacturing and marketing pharmaceutical products. Petitioner was subject to New York State sales and use tax under Articles 28 and 29 of the New York State Tax Law during the period March 1, 1996 through February 28, 1999.
- 2. As part of its marketing efforts for its pharmaceutical products during the audit period, petitioner distributed samples of drugs and medicines free of charge ("Sample Drugs") to physicians and other health care providers in New York State and elsewhere. The Sample Drugs consisted of medically active ingredients and other chemical ingredients (which, together with the medically active ingredients, comprised "medical compounds"). The Sample Drugs were distributed in a variety of forms, including powders, tablets, creams, gels and liquids. The Food and Drug Administration mandated that the Sample Drugs be delivered in an unadulterated state, in accordance with Federally mandated Good Manufacturing Practices.
- 3. The use of the Packaging Materials in the distribution of the Sample Drugs was the method by which petitioner sought to, and did, comply with the Federally mandated Good Manufacturing Practices. The Packaging Materials consisted of bottles, boxes, blister packs, plastic tubes, cotton, safety closure covers, safety seals, protective wrapping and labels affixed to the foregoing.

- 3. In accordance with the Federally mandated Good Manufacturing Practices, petitioner was required to maintain the Sample Drugs in a pure and unadulterated state and to ensure that they remained free from contamination. The Packaging Materials were used to contain the Sample Drugs, ensure that they remained free from contamination and tampering, and maintain their purity. The Packaging Materials were also used to provide a means of delivering the Sample Drugs to physicians and other health care providers and for the physicians and other health care providers to distribute the Sample Drugs to their patients.
- 4. The Packaging Materials were not used to administer the Sample Drugs and did not include items such as hypodermic needles used for injection or applicators used for applying creams or gels. However, the Packaging Materials were used to deliver measured quantities of the Sample Drugs to physicians and other health care providers and for these individuals to distribute the Sample Drugs to their patients. The Packaging Materials differed only in size, but not nature, from the packaging materials used when drugs and medicines are delivered to a consumer in a retail sale.
- 5. In addition to the Federally mandated Good Manufacturing Practices relating to the packaging of the Sample Drugs, Federal law and regulations required that the Sample Drugs be accompanied by printed information describing the proper usage, dosage, possible adverse reactions and other information required by the United States Food and Drug Administration concerning the Sample Drugs ("Required Information"). Petitioner caused the Required Information to be printed either (i) directly on the Packaging Materials containing the Sample Drugs (on the boxes, bottles, plastic tubes and/or labels), (ii) on the Informational Inserts accompanying the Sample Drugs and Packaging Materials, or (iii) on both the Packaging Materials containing the Sample Drugs and the Informational Inserts accompanying the Sample

Drugs. The Inserts consisted of free-standing printed informational inserts that contained all or a portion of the Required Information concerning the Sample Drugs that they accompanied. The Inserts were identical to the informational inserts delivered to a consumer upon a retail sale of drugs and medicines.

- 6. The Packaging Materials and Informational Inserts utilized to distribute free samples of Cleocin T Gel and Cleocin T Lotion are representative of the Packaging Materials and Informational Inserts. The Sample Drugs, Packaging Materials and Informational Inserts (collectively, the "Sample Units") used for the delivery of Cleocin T Gel Sample Drugs consisted of a printed cardboard box containing (i) sixty foil and plastic sample packets each containing .03125 ounces of Cleotin T Gel and (ii) one folded printed paper insert describing the use, pharmacology, indications, usage, contraindications, warnings, drug interactions and other relevant information required by the United States Food and Drug Administration. The Sample Drugs, Packaging Materials and Informational Inserts used for the delivery of Cleocin T Lotion Sample Drugs consisted of a printed cardboard box containing (i) twenty-four plastic sample bottles each containing seven milliliters of Cleotin T Lotion and (ii) one folded printed paper insert describing the use, pharmacology, indications, usage, contraindications, warnings, drug interactions and other relevant information required by the United States Food and Drug Administration.
- 7. Petitioner caused the Sample Units to be delivered into New York State in connection with its solicitation of sales of its pharmaceutical products. In all instances, the Sample Drugs were prepared for distribution to physicians and other health care providers with the Packaging Materials and Inserts prior to their being "hand carried" or shipped into New York State. Under these circumstances, the sample Drugs were contained in the Packaging Materials and packaged

with the Inserts when they entered New York State. In most instances, the Sample Units were shipped from outside New York State in corrugated paperboard cartons, using a common carrier, to petitioner's sales and marketing representatives who "hand carried" the Sample Units to physicians and other health care providers in New York State. In all other instances, such as in the case of Sample Units containing either controlled substances or temperature-sensitive medical compounds, the Sample Units were shipped in corrugated paperboard cartons from outside New York State directly to physicians and other health care providers in New York State using a common carrier.

- 8. On July 26, 2000, petitioner filed an Application for Credit or Refund of Sales or Use Tax with the Division of Taxation ("Division") for the sales and use tax paid during the audit period on the Sample Units (the "Refund Claim"). In the Refund Claim, petitioner claimed a refund of sales and use tax paid in the amount of \$176,113.00. The Refund Claim did not include the cost to petitioner of the corrugated paperboard cartons in which the Sample Units were shipped to sales and marketing representatives and physicians and other health care providers.
- 9. In a notice dated November 28, 2000, the Division partially approved the Refund Claim in the amount of \$126,771.00, which was attributable to the portion of the cost of the Sample Units attributable to the Sample Drugs, and partially denied the Refund Claim in the amount of \$49,342.00. The portion of the Refund Claim that was denied was attributable to the sales or use tax paid on the Packaging Material and Inserts that were distributed by petitioner to physicians and other health care providers in New York State during the audit period.
- 10. The amount of the sales or use tax that petitioner paid during the audit period relating to its New York State use of the Packaging Materials was \$43,914.00. The amount of the sales

or use tax that petitioner paid during the audit period relating to its New York State use of Inserts was \$5,428.00.

- 11. If petitioner had separately purchased the Packaging Materials and Inserts for delivery in New York State and subsequently used such Packaging Materials and Inserts in the distribution of Sample Drugs, the exemption provided by section 1115(a)(3) of the Tax Law for drugs and medicines would have been inapplicable to such purchases.
- 12. No sales or use tax is collected or legally due with respect to the packaging materials and informational inserts delivered to a consumer upon a retail sale of drugs and medicines, which are equivalent to the Packaging Materials and Inserts distributed free of charge with Sample Drugs.

# **SUMMARY OF THE PARTIES' POSITIONS**

charge to doctors are not subject to use tax pursuant to Tax Law § 1115(a)(3), neither should the Packaging Materials and Informational Inserts be subject to use tax since such materials are a critical element of the samples. Citing *Burger King v. State Tax Commn.* (51 NY2d 614, 435 NYS2d 689) and *Celestial Foods of Massapequa Corp. v. New York State Tax Commn.* (63 NY2d 1020, 484 NYS2d 509), petitioner argues that its Packaging Materials and Informational Inserts are not simply items of overhead supplied for the convenience of its customers, but are an integral component of the samples since the samples could not be legally or safely transported or used without the Packaging Materials and Inserts. Petitioner also discusses an advisory opinion issued by the Division (TSB-A97[62]S) wherein the Division held that labels attached to drugs and medicines and informational pamphlets accompanying the drugs and medicines were exempt from sales tax because such materials were a critical element of the drugs and medicines that

were to be sold. Petitioner asserts that although the courts created the critical element test in answer to a sale for resale situation there is no logical reason not to apply the test to other sales tax exemptions. Finally, petitioner argues that the Division, recognizing that the Packaging Materials and Inserts are not subject to sales tax when sold to the ultimate consumer, must apply such exemption equally to the use tax.

14. The Division argues that the Packaging Materials and Informational Inserts are not a critical element of the drugs and medicines given by petitioner to the doctors and that, even if the Packaging Materials and Inserts were a critical element, that does not make them drugs and medicines and they are still subject to the use tax. The Division asserts that the critical element cases relied upon by petitioner apply only to containers and not all of the items at issue are containers. The Division also contends that the critical element test applies only to sales for resale and since neither the drugs and medicines nor the Packaging Materials and Inserts in this case are resold, the case law is simply inapplicable. The Division in particular discusses the Court of Appeals holding in *Burger King* and stresses that the Court specifically stated that the packaging never became part of the product sold and was exempt because the packaging was sold as packaging for resale. The Division contends that the packaging exemption exists because not all packaging is deemed resold and therefore a separate exemption is required. The Division also argues that it is not required to hold the Packaging Materials and Inserts exempt from use tax simply because they are exempt from sales tax when resold. The Division cites a 1965 opinion of counsel that held such packaging materials are not exempt from use tax despite the legal requirements that they be used to distribute drugs and medicines. Finally the Division argues that exemptions from taxation are to be narrowly construed and petitioner has presented no statutory or case law in support of its position.

### **CONCLUSIONS OF LAW**

A. Tax Law § 1105(a) imposes a sales tax on "[t]he receipts from every retail sale of tangible personal property, except as otherwise provided in this article." All sales of tangible personal property are presumptively subject to tax pursuant to Tax Law §1132(c) "until the contrary is established." Petitioner contends that the Packaging Materials and Informational Inserts used in the distribution of sample drugs and medicines are exempt from sales and use tax under Tax Law § 1115(a)(3). Where a taxpayer claims an exemption from tax, the burden is on the taxpayer to show that its interpretation of the statute is the only reasonable interpretation or that the Division's interpretation is unreasonable (*Matter of Grace v. State Tax Commn.*, 37 NY2d 193, 371 NYS2d 715, *Iv denied* 37 NY2d 708, 375 NYS2d 1027).

B. Pursuant to Tax Law § 1132(c)(1), petitioner bears the burden of establishing by clear and convincing evidence that the denial of the tax refund was erroneous ( *Matter of Rizzo v. Tax Appeals Tribunal*, 210 AD2d 748, 621 NYS 2d 115; *Matter of Mobley v. Tax Appeals Tribunal*, 177 AD2d 797, 799, 576 NYS 2d 412, *appeal dismissed* 79 NY2d 978, 583 NYS2d 195; *Matter of Surface Line Operators Fraternal Line Organization v. Tully*, 85 AD2d 858, 446 NYS2d 451). Furthermore, a presumption of correctness attaches to a refund denial issued by the Division, and the taxpayer must overcome this presumption (*see, Matter of Suburban Carting Corporation*, Tax Appeals Tribunal, May 7, 1998, citing *Matter of Tavolacci v. State Tax Commn.*, 77 AD2d 759, 431 NYS2d 174; *Matter of Leogrande*, Tax Appeals Tribunal, July 18, 1991, *confirmed* 187 AD2d 768, 589 NYS2d 383, *Iv denied* 81 NY2d 704, 595 NYS2d 398).

C. Section 1115(a)(3) of the Tax Law provides an exemption from sales tax for:

drugs and medicines intended for use, internally or externally, in the cure, mitigation, treatment or prevention of illnesses or diseases in human beings, medical equipment (including component parts thereof) and supplies required for such use or to correct or alleviate physical incapacity, and products consumed by

humans for the preservation of health but not including cosmetics or toilet articles notwithstanding the presence of medical ingredients therein or medical equipment (including components parts thereof) and supplies, other than such drugs and medicines, purchased at retail for use in performing medical and similar services for compensation.

- D. Petitioner is in the business of developing, manufacturing and marketing pharmaceutical products. The parties stipulated that, on a retail sale within New York State, no sales or use tax would be collected or would be legally due with respect to the packaging materials and informational inserts delivered to a consumer upon the sale of the drugs and medicines, pursuant to Tax Law § 1115(a)(3). The packaging materials and informational inserts which accompany a retail sale of drugs and medicines are the equivalent to the Packaging Materials and Informational Inserts distributed free of charge with the Sample Drugs. To promote its business, petitioner provides physicians and other health care providers within New York State sample drugs and medicines that can then be given to their patients. The Division asserts that the use by petitioner of its products in this manner in New York State is subject to use tax pursuant to Tax Law § 1110 which provides in relevant part:
  - (a) Except to the extent that property or services have already been or will be subject to the sales tax under this article, there is hereby imposed on every person a use tax for the use within this state . . . except as otherwise exempted under this article, (A) of any tangible personal property purchased at retail, (B) of any tangible personal property . . . manufactured, processed or assembled by the user, (i) if items of the same kind of tangible personal property are offered for sale by him in the regular course of business. . . .

There is no doubt that the drugs and medicines and the Packaging Materials and Inserts provided by petitioner to physicians and other health care providers are tangible personal property and that these are the same kinds of items that accompany a retail sale of the same drugs and medicines. Therefore, unless such items are specifically excluded or exempted, they would be subject to the use tax. With regard to the drugs and medicines themselves there is no question that they are

exempt from tax pursuant to Tax Law § 1115(a)(3). The issue to be determined is whether the Packaging Materials and Inserts are also exempt from tax pursuant to Tax Law § 1115(a)(3) because of their close association with the drugs and medicines.

E. It is first necessary to review the provision of the Tax Law under which the packaging materials accompanying or containing drugs and medicines are not taxed when these materials are sold to retailers and ultimately to consumers. The packaging materials are either exempt from tax as containers (Tax Law § 1115[a][19]) or excluded from tax as a sale for resale. Contrary to the Division's assertions that the packaging materials are exempt from tax as containers under Tax Law § 1115(a)(19) are a 1965 Opinion of Counsel (November 16, 1965, NYS Tax Bulletin NO. 1965-4) and a 1997 Advisory Opinion (TSB-A-97[62]S) wherein it is evident that the Division itself has never considered such materials as exempt from tax under Tax Law § 1115(a)(19). The Opinion of Counsel proceeds under the assumption that the packaging materials are exempt as a sale for resale. However, this opinion was issued prior to the enactment of the container exemption in 1975 (L 1975, ch 581). In the Advisory Opinion (TSB-A-97[62]S) the Division, citing *Matter of Gem Stores* (Tax Appeals Tribunal, October 14, 1988), held that labels attached to drugs and medicines and the explanatory material accompanying the drugs and medicines were a critical element of the drugs and medicines. Specifically, the opinion stated:

a label is a critical element of the product sold, if it has a critical quality useful to the final customer and is not just an expense or part of the general overhead which the retailer chooses in order to profitably carry on in business. The labels and pamphlets produced by Petitioner do form a critical element of the product sold, i.e., the medication. The label and accompanying pamphlet contain critical information which is useful to the customer for the proper usage of the medication

While not bound by this advisory opinion, it is highly persuasive and in conformity with Matter of Gem Stores (supra) and Matter of Burger King v. State Tax Commn (51 NY2d 614, 435 NYS2d 689) which was extensively discussed in *Gem Stores*. It was in *Matter of Burger* **King** (supra) that the Court of Appeals determined that the packaging materials used by Burger King, such as hamburger wrappers, were a critical element of the product sold to Burger King's customers (id., 435 NYS2d at 693). In reaching this determination the Court found that fast food restaurants did not sell tangible personal property, but in reality sold a hybrid product consisting of restaurant food and service (id., 435 NYS2d at 691, 692). Having found that Burger King did not sell tangible personal property, the packaging materials utilized could not then be exempt as a "physical component part" of such property pursuant to Tax Law § 1101(b)(4)(ii)(A). What the Court actually determined was that, as a critical element of the goods sold, the packaging materials were simply a part of the goods and therefore also excluded from tax as a sale for resale pursuant to Tax Law § 1101(b)(4)(i)(A) (id., 435 NYS2d at 693). While not explicitly stated, the implication of the Advisory Opinion is not that labels and informational materials sold with drugs and medicines are exempt as sales for resale, but rather that such materials are actually a part of the drugs and medicines. Therefore, the labels and informational materials are exempt from tax for the same reason the drugs and medicines are exempt from tax, i.e., Tax Law § 1115(a)(3). The facts in this matter are also comparable to those in **Burger King** in that what a consumer receives as a final product is not only the drugs themselves but the information necessary to safely use the drugs and medicines.

The Advisory Opinion does not address the issue of the containers of the drugs and medicines. Such containers are provided primarily for safety reasons and to ensure that the drugs and medicines delivered to the consumers are unadulterated as required by the FDA.

Based upon the reasoning utilized to determine that the labels and informational materials are a critical element of the drugs and medicines, the same determination is reached with regard to the Packaging Materials and Informational Inserts.

- F. Having found that the packaging materials and inserts are a critical element of the drugs and medicines when sold for resale, the question becomes whether the Packaging Materials and Inserts are also a critical element of the sample drugs and medicines. The question must be answered in the affirmative as it is illogical to conclude that somehow the Packaging Materials and Inserts become separated from the drugs and medicines because they are given away instead of sold. The 1965 Opinion of Counsel cited by the Division does state that packaging and information materials given away with drugs and medicines are not exempt despite the close relationship to the drugs and medicines and the statutory requirements that they accompany the drugs and medicines. However, this opinion was issued 15 years before the Court of Appeals enunciated the critical element test in the *Matter of Burger King v. State Tax* Commn (supra), and some 23 years prior to Matter of Gem Stores (supra). Furthermore, the 1997 Advisory Opinion holding that in a resale situation the pamphlets and information materials are a critical element of the drugs and medicines is in direct contradiction to the Opinion of Counsel. Therefore, I do not find the Opinion of Counsel persuasive argument as to the current law on the question of whether the Packaging Materials and Inserts are a critical element of the drugs and medicines.
- G. The final question is whether the finding that the Packaging Materials and Inserts are a critical element of the sample drugs and medicines precludes the imposition of use tax. It is determined that it does. Again based on the reasoning set forth above, the Packaging Materials and Inserts have become part of the drugs and medicines and there is no use which would be

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subject to tax. The Division's argument that Tax Law § 1118 requires that use tax be imposed

because sales tax would be imposed upon the purchase of such materials by an in-state

pharmaceutical company that was going to give them away is not relevant to the current analysis

because no sales tax would be imposed (see, Matter of Burger King, supra). The packaging

materials are actually a part of the drugs and medicines making them exempt from taxation in

either situation. The Division also relies on the Opinion of Counsel on this point, which has

previously been determined to be unpersuasive. As further evidence that the Opinion of Counsel

is no longer indicative even of the Division's position on this issue in this case, the opinion states

that the inert ingredients of the drugs and medicines themselves would be subject to the use tax

in the present situation, yet there is no attempt by the Division in this matter to tax those

ingredients.

H. In conclusion, petitioner in this matter was seeking an exemption from tax and

therefore was required to prove that its interpretation of the Tax Law was the only reasonable

interpretation (see, Matter of Grace v. State Tax Comm., supra; Matter of Federal Insurance

Co. v. State Tax Comm., 146 AD2d 888, 536 NYS2d 595). Petitioner has met this burden in

that the Packaging Materials and Informational Inserts are found to be a critical element of the

sample drugs and medicines and as such are exempt from the use tax pursuant to Tax Law §

1115(a)(3).

I. The petition of Pharmacia & Upjohn Company is granted.

DATED: Troy, New York

January 9, 2003

/s/ Thomas C. Sacca

ADMINISTRATIVE LAW JUDGE